



PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 5/00	A1	(11) International Publication Number: WO 96/41649 (43) International Publication Date: 27 December 1996 (27.12.96)
(21) International Application Number: PCT/US96/09125 (22) International Filing Date: 5 June 1996 (05.06.96) (30) Priority Data: 114093 9 June 1995 (09.06.95) IL (71) Applicant (for all designated States except US): MIGADA, INC. [US/US]; 482 Hudson Terrace, Englewood Cliffs, NJ 07632 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): SHEMESH, Eli [IL/IL]; 59 Kinneret Street, 77700 Ashdod (IL). NIJINSKI, Jacob [IL/IL]; 5/3 Kaftor Haholot Street, 77569 Ashdod (IL). (74) Agents: GALLOWAY, Peter, D.; Ladas & Parry, 26 West 61st Street, New York, NY 10023 (US) et al.		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: BLUNT CANNULA CONSTRUCTION FOR MULTIPLE APPLICATIONS <div data-bbox="347 1155 1305 1386" data-label="Image"> </div> (57) Abstract <p>This invention discloses a cannula (10) having a hub (11) at one end integrally formed with a Luer locking element (12) for attachment to a syringe (2), and a tapered section (14) terminating in a blunt tip (15) at the opposite end; characterized in that said tapered section (14) is of a length of 30 mm to 100 mm, and has an outer diameter of at least 3 mm at its large diameter end tapering therefrom to an outer diameter of at least 0.8 mm at the blunt tip (15), the cannula (10) being of a plastic material sufficiently stiff and tapered to enable the cannula (10) to be used not only for insertion through a pre-slitted, self-sealing plug, but also for puncturing a vial for withdrawing liquid therefrom, and also for withdrawing liquid from an ampule.</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic			SE	Sweden
CG	Congo	KR	Republic of Korea	SG	Singapore
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LR	Liberia	SZ	Swaziland
CS	Czechoslovakia	LT	Lithuania	TD	Chad
CZ	Czech Republic	LU	Luxembourg	TG	Togo
DE	Germany	LV	Latvia	TJ	Tajikistan
DK	Denmark	MC	Monaco	TT	Trinidad and Tobago
EE	Estonia	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	UG	Uganda
FI	Finland	ML	Mali	US	United States of America
FR	France	MN	Mongolia	UZ	Uzbekistan
GA	Gabon	MR	Mauritania	VN	Viet Nam

BLUNT CANNULA CONSTRUCTION FOR MULTIPLE APPLICATIONS

The present invention relates to a cannula construction, and more particularly to a blunt cannula of a construction enabling it to be used in a wide variety of different medical applications.

It is highly desirable to use blunt cannulas made of stiff plastic material as a replacement for metal needles in syringes in order to minimize the possibility of accidental needle sticks which may cause infection of a person handling an infected needle. Such blunt cannulas are now used to penetrate pre-slitted rubber plugs which self-seal as soon as the blunt cannula has been removed. The blunt cannula of one manufacturer includes a cylindrical section of 10 mm in length and a tapered section of 2-3 mm in length, the tapered section having an outer diameter tapering from 2.0 to 1.8 mm and an inner diameter tapering from 1.5 to 1.2 mm. The blunt cannula of another manufacturer includes a cylindrical section of 13 mm in length and formed with a rounded tip rather than with a tapered section, the rounded tip having an outer diameter of 1.8-2.0 mm. These known blunt cannulas have heretofore been used for penetrating pre-slitted, self-sealing rubber plugs, such as provided at injection sites for injecting or withdrawing liquids.

Metal needles attached to syringes are also commonly used for puncturing the plug or septum of a vial in order to withdraw liquid from the vial. Recently, a two-part cannula has been constructed for this application, including a pointed tip part slidably received within a blunt cannula part, such that the pointed tip part is used to puncture the plug of the vial and is retained in place, while the blunt cannula part is used for withdrawing the liquid from the vial via the pointed tip part. Such a two-part construction, however, is quite costly.

Metal needles attached to syringes are also used for withdrawing liquids from ampules.

An object of the present invention is to provide a blunt cannula construction enabling it to have more universal application, not only for insertion through a pre-slitted, self-sealing plug, but also for puncturing unslitted plugs or septums in vials and for withdrawing liquids from ampules. Another object of the invention is to provide a syringe including the novel blunt cannula construction. Further objects are to provide a method which avoids the need of a metal needle for withdrawing liquids from vials closed by unslitted plugs or septums, or from ampules, as well as for withdrawing or injecting liquids via pre-slitted rubber plugs.

According to the present invention, there is provided a cannula having a hub at one end integrally formed with a Luer locking element for attachment to a syringe, and a tapered section terminating in a blunt tip at the opposite end; characterized in that the tapered section is of a length of 30-100 mm, and has an outer diameter of at least 3 mm at its large diameter end tapering therefrom to an outer diameter of at least 0.8 mm at the blunt tip, the cannula being of a plastic material sufficiently stiff and tapered such as to enable the cannula to be used not only for insertion through a pre-slitted, self-sealing plug, but also for puncturing a vial for withdrawing liquid therefrom, and also for withdrawing liquid from an ampule.

According to further features in the described preferred embodiment, the inner diameter of the blunt tip is at least 0.3 mm, preferably 0.3 to 0.7 mm. In addition, the cannula further includes a cylindrical section between the hub and the tapered section, the cylindrical section having an outer diameter equal to that of the enlarged diameter end of the tapered section. Preferably, the cylindrical section has a length of at least 2 mm, preferably 3-10 mm.

It will be seen that the dimensions of the novel blunt cannula constructed in accordance with the present invention are substantially different from those of the blunt cannulas heretofore used only for penetrating pre-slitted rubber plugs; thus, the novel blunt cannula has a much longer tapered section, longer by at least one order of magnitude, and a significantly smaller blunt tip, than the blunt cannulas heretofore used only with respect to pre-slitted rubber plugs. It was surprisingly found that cannulas constructed in accordance with the foregoing features may be used not only for penetrating pre-slitted rubber plugs as the existing blunt cannulas, but also for vials, and for withdrawing liquids from a vial or from an ampule, heretofore done by metal needles.

Further features and advantages of the invention will be apparent from the description below.

The invention is herein described, by way of example only with reference to the accompanying drawings, wherein:

Fig. 1 illustrates a syringe including a cannula constructed in accordance with the present invention;

Fig. 2 is an enlarged side elevational view of the cannula in the syringe of Fig. 1;

Fig. 3 is a sectional view of the cannula of Fig. 2;

Fig. 4 illustrates a syringe including a cannula according to Fig. 1 and a protector sleeve on the cannula;

Fig. 5 is a cross-sectional view of the protector sleeve of Fig. 4; and

Figs. 6, 7, 8 and 9 illustrate a syringe including a cannula constructed as illustrated in Figs. 2 and 3 for use in a number of diverse applications.

With reference first to Fig. 1, there is illustrated a syringe, generally designated 2, including a barrel 3 receiving a plunger 4 having a plunger head 5 movable towards and away from an end wall 6 of the barrel. The plunger assembly has a thumbrest 7, and the barrel 3 has finger flanges 8, engageable by the thumb and fingers of the user for moving the plunger towards the end wall 6.

End wall 6 is integrally formed with a standard Luer connector normally used for attaching a standard metal hypodermic needle. In this case, connector 9 of the syringe 2 is used for attaching the cannula 10 constructed in accordance with the present invention.

Figs. 2 and 3 more particularly illustrate the construction of cannula 10. It includes a hub 11 at one end having an outer cylindrical configuration and integrally formed with a female Luer locking element 12 cooperable with a male Luer locking element (not shown) in connector 9. Cannula 10 further includes a short cylindrical section 13, and a long tapered section 14 terminating in a blunt tip 15 at the end opposite to that of the hub 11.

The tapered section 14 includes a first segment 14a at the larger-diameter end of that section integrally joined to a second segment 14b at the smaller-diameter end of that section. The smaller-diameter segment 14b has a longer length and a larger taper than the larger-diameter segment 14a.

Preferably, the hub 11 should have an axial length of 7-10 mm, an outer diameter of 6 mm, and an inner diameter of 4.4 mm. This will make the cannula attachable to a standard Luer connector on a syringe. The short cylindrical section 13 is used for receiving a protective sleeve (not shown) which is removed when the cannula is to be used.

The dimensions of sections 13 and 14 of the cannula should be as follows: The cylindrical section 13 should have an axial length of at least 2 mm, preferably 3-10 mm, and an outer diameter of at least 3 mm, preferably 3-10 mm; the tapering section 14, including its two segments 14a, 14b, should have an axial length of 30-100 mm; and blunt tip 15 should have an outer diameter of at least 0.8 mm, preferably 0.8-1.3 mm.

In a preferred construction, the cylindrical section 13 has an axial length of 3 mm and an outer diameter of 5 mm; and the tapering section 14 has a length of 50-55 mm, an outer diameter tapering from 5.0 mm at large-diameter end to 1.1 mm at its blunt tip 15. Preferably, the

taper angle " α " of the outer surface of segment 14a should be 3° , and the taper angle (β) of segment 14b should be 5° . The inner diameter of the blunt tip 15 is at least 0.3 mm, preferably 0.3-0.7 mm, best results being obtained when it is about 0.5 mm.

The complete cannula 10 illustrated in Figs. 1 and 2 is preferably made of a stiff plastics material, preferably polyethylene, nylon, polycarbonate, polyvinylchloride or ABS.

Fig. 4 illustrates the syringe 2 with the cannula 10 applied thereto, and with a protector sleeve 20 applied over the cannula 10. Thus, the protector sleeve 20 has an inner diameter equal to the outer diameter of the cylindrical section 13 of the cannula 10, and has a length greater than the length of the tapered section 14 together with the cylindrical section 13 of the cannula; that is, the length of protector sleeve 20 should be at least 35 mm, and should project past the blunt tip 15 of the cannula by at least 5 mm.

As seen in Fig. 5, protector sleeve 20 includes opposed flattened surfaces 21, 22 engageable with opposed flattened surfaces of the cylindrical section 13 of the cannula to permit the protector sleeve to rotate the cannula when attaching it to the syringe 10 or when detaching it from the syringe.

Figs. 6-9 illustrate the universal applicability of the blunt cannula when constructed as illustrated in Figs. 1-3 according to the dimensions described above.

Thus, Fig. 6 illustrates the cannula 10, where attached to syringe 2, for withdrawing a liquid from a vial 30 closed by an unslitted rubber plug or septum 31. As mentioned earlier, presently used for this purpose is a two-part cannula construction which includes a pointed tip part slidably received within a blunt cannula part, such that the pointed tip part is used to puncture the unslitted plug and, when while retained in place, the blunt cannula part is used for withdrawing the liquid from the vial via the pointed tip part. It was surprisingly found that a cannula constructed as illustrated in Figs. 1-3, and according to the dimensions described above, could be used for puncturing and penetrating an unslitted plug or septum 31 in a vial 30 for withdrawing the liquid therefrom thereby eliminating the need for the expensive two-part cannula. This application of the novel cannula is illustrated in Fig. 6.

Fig. 7 illustrates another application of the above-described blunt cannula, namely for withdrawing a liquid from an ampule 35 normally closed by an integrally formed cover (not shown). Thus, after the cover has been broken away, a syringe 2 equipped with a blunt cannula 10 as described above may also be used for withdrawing the liquid from the ampule via the cannula.

Fig. 8 illustrates the use of a syringe equipped with a cannula 10 as described above for injecting liquid or withdrawing liquid with respect to an injection site, generally designated 40, via a pre-slitted plug 41. Thus, the blunt cannula of the present invention can also be used in this application equally well as the previously-known blunt cannulas which included a much shorter tapering section, as described above.

Fig. 9 illustrates a similar application of a syringe equipped with a cannula 10 for introducing a liquid into, or withdrawing a liquid from, an infusion bag 50 via an injection site 51. In this case, the injection site 51 includes a pre-slitted plug 52 and an unslitted separator layer, both of which are penetrated by the blunt cannula 10 attached to the syringe 2.

While the invention has been described with respect to one preferred embodiment, including several applications of such an embodiment, it will be appreciated that further variations, modifications and applications of the invention may be made.

CLAIMS

1. A cannula having a hub at one end integrally formed with a Luer locking element for attachment to a syringe, and a tapered section terminating in a blunt tip at the opposite end; characterized in that said tapered section is of a length of 30-100 mm, and has an outer diameter of at least 3 mm at its large diameter end tapering therefrom to an outer diameter of at least 0.8 mm at the blunt tip, the cannula being of a plastic material sufficiently stiff and tapered to enable the cannula to be used not only for insertion through a pre-slitted, self-sealing plug, but also for puncturing a vial for withdrawing liquid therefrom, and also for withdrawing liquid from an ampule.
2. The cannula according to Claim 1, wherein the inner diameter of the blunt tip is at least 0.3 mm.
3. The cannula according to either of Claims 1 or 2, wherein the cannula further includes a cylindrical section between said hub and said tapered section, said cylindrical section having an outer diameter equal to that of the enlarged diameter end of the tapered section.
4. The cannula according to Claim 3, wherein said cylindrical section has an outer diameter of at least 3 mm.
5. The cannula according to Claim 4, wherein said cylindrical section has a length of at least 2 mm.
6. The cannula according to any one of Claims 1-5, wherein said tapered section has a first segment at its larger-diameter end integrally joined to at least one second segment at its smaller-diameter end of longer length, and of a larger taper angle, than said first segment.
7. The cannula according to any one of Claims 1-6, wherein said hub has an outer surface of cylindrical configuration having an outer diameter of 6 mm and an inner diameter of 4.4 mm.

8. The cannula according to any one of Claims 1-7, wherein the length of said tapered section is 50-55 mm.
9. The cannula according to any one of Claims 1-8, wherein the outer diameter of said blunt tip is 0.8-1.3 mm.
10. The cannula according to any one of Claims 1-9, wherein the inner diameter of said blunt tip is 0.3 - 0.7 mm.
11. The cannula according to any one of Claims 3-10, further including a cylindrical protector sleeve having an inner diameter corresponding to the cylindrical section of the cannula and a length to project outwardly of said tapered section of the cannula.
12. The cannula according to Claim 11, wherein said cylindrical protector sleeve includes opposed flattened surfaces on its inner face engageable with opposed flattened surfaces on the outer face of said cylindrical section of the cannula to permit the protector sleeve to rotate the cannula when attaching the cannula to a syringe via said Luer locking element, or when detaching the cannula therefrom.
13. A syringe including a male Luer locking element, and a cannula according to any one of Claims 1-12 including a female Luer locking element attached to the male Luer locking element of said syringe.
14. A method of withdrawing a liquid from a vial closed by a plug, comprising: providing a syringe according to Claim 13; forcing the blunt tip of its cannula to puncture and penetrate said plug; and operating the syringe to withdraw the liquid from the vial via said cannula.
15. A method of withdrawing liquid from an ampule, comprising: providing a syringe according to Claim 13; breaking off the top of the ampule; inserting the blunt tip of its cannula into the ampule; and operating the syringe to withdraw the liquid from the ampule via said cannula.

16. A method of injecting a liquid or withdrawing a liquid via an injection site of a fluid containing bag closed by a pre-slitted rubber plug, comprising: providing a syringe according to Claim 13; forcing the blunt tip of the cannula through said pre-slitted plug; and operating the syringe to inject a liquid or withdraw a liquid via said cannula.

17. The method according to Claim 16, wherein the injection site of the fluid containing bag is also closed by an unslitted separator layer; and the blunt tip of the cannula is forced through both said pre-slitted plug and said unslitted separator layer.

1/4

FIG. 1

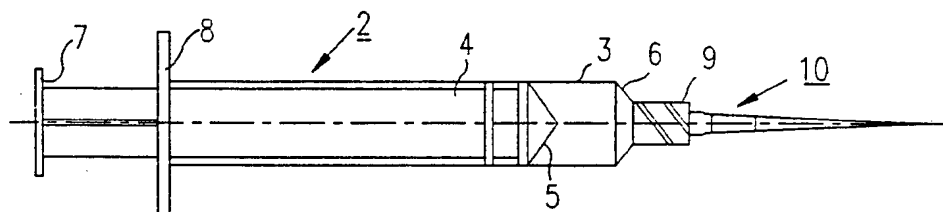


FIG. 2

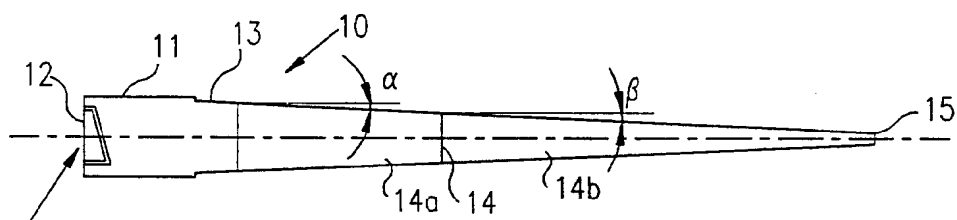


FIG. 3

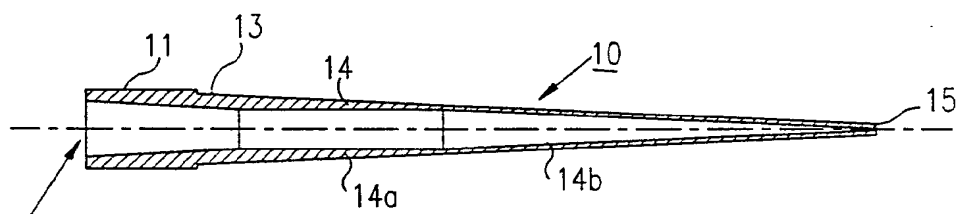


FIG. 4

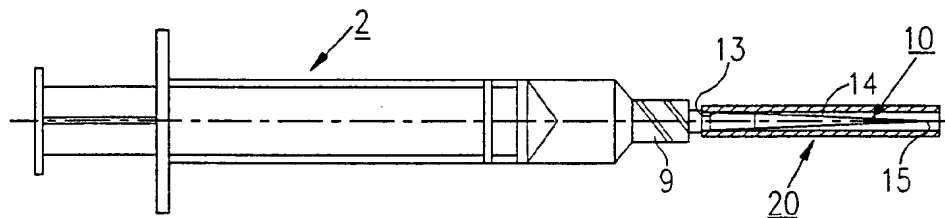
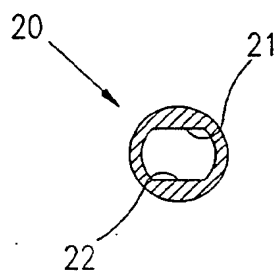
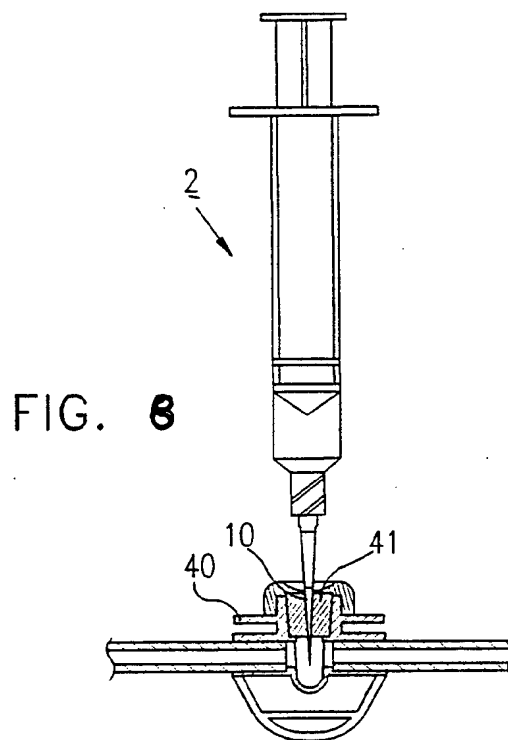
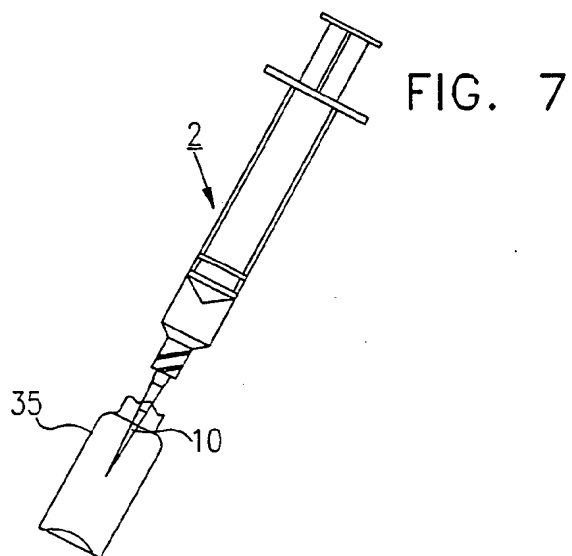
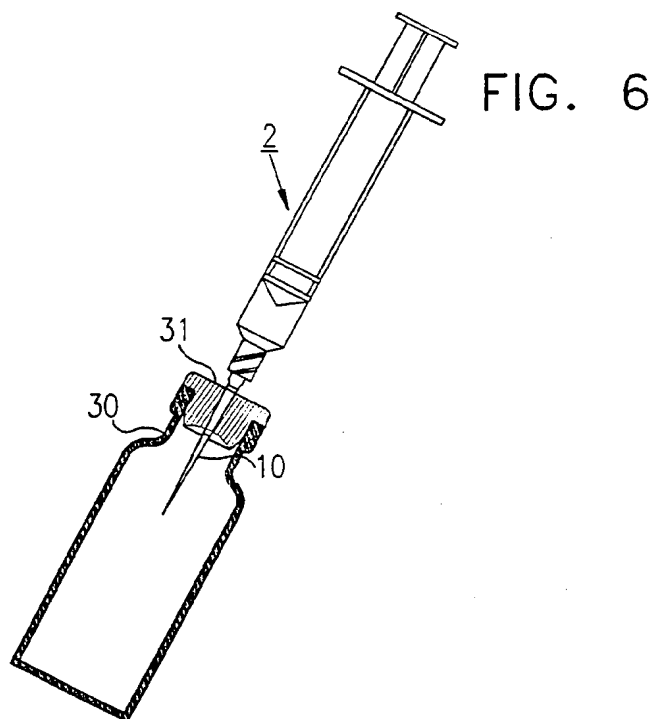


FIG. 5



3/4



4/4

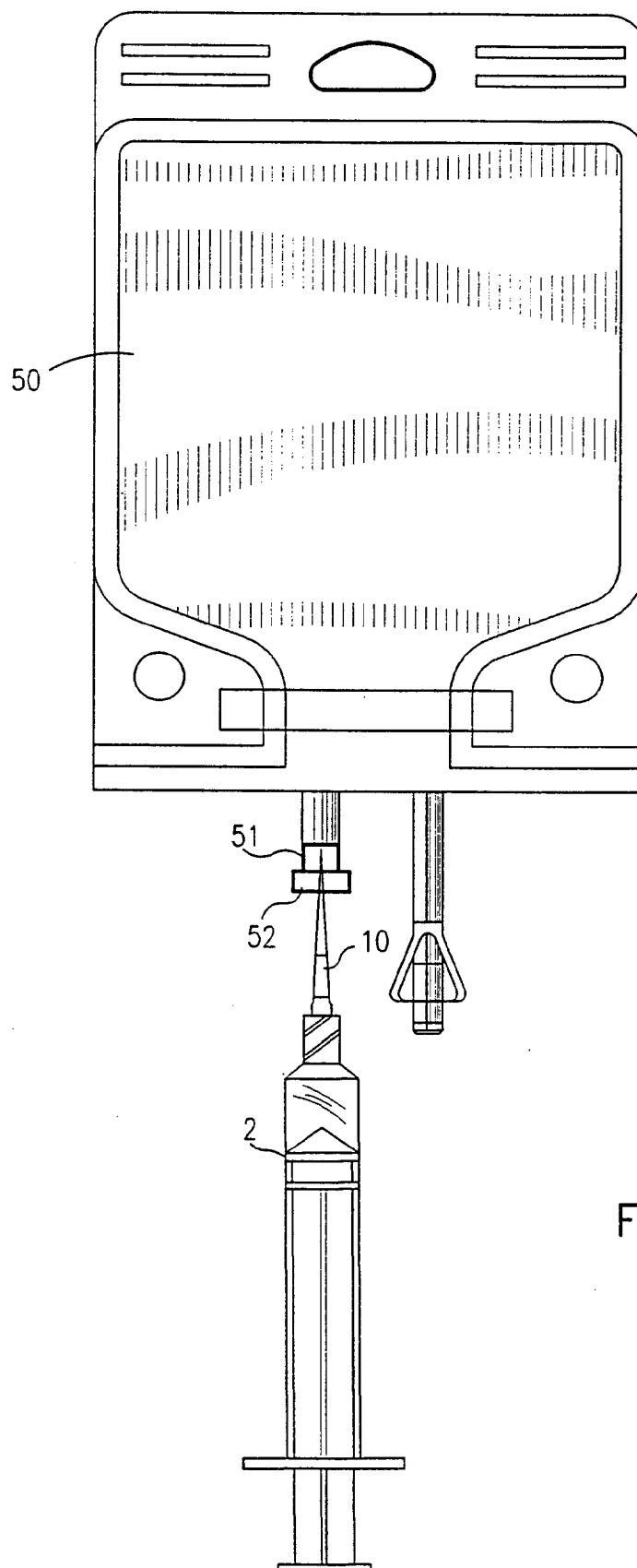


FIG. 9

INTERNATIONAL SEARCH REPORT

 International application No.
PCT/US96/09125

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 5/00

US CL : 604/264

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/264, 272-274

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A. 5,178,607 (LYNN ET AL.) 12 January 1993, see Figs. 24-29, column 16 lines 9-67, and column 17 lines 32-47.	1-3 ----- 4, 5
A	US, A. 2,906,423 (SANDHAGE) 29 September 1959, see Fig. 8.	1-3
X	US, A. 4,345,596 (YOUNG) 24 August 1982, see Fig. 1.	1-3
A	US, A. 5,328,041 (HOOK ET AL.) 12 July 1994, see Fig. 3.	1-3
A, P	US, A. 5,458,614 (HUMPHREY) 17 October 1995, see column 2 lines 20-42.	1-3

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Z" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

30 AUGUST 1996

Date of mailing of the international search report

04 OCT 1996

 Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3590

 Authorized officer *Diane B. Smith for*
DEBORAH BLYVEIS

Telephone No. (703) 308-2110